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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,904	11/27/2000	Michael H. Julius	47841/00063	4246
33721	7590	03/08/2005	EXAMINER	
TORYS LLP 79 WELLINGTON ST. WEST SUITE 3000 TORONTO, ON M5K 1N2 CANADA			TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 03/08/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

716

Office Action Summary

Application No.

09/721,904

Applicant(s)

JULIUS ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 170-176, 180, 199-202, 222, 223, 226-230 and 256-312 is/are pending in the application.
- 4a) Of the above claim(s) 256-312 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 170-176, 180, 199-202, 222, 223, 226-230 and 256-312 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the amendment, received 12/16/04.

Claims 170-176, 180, 199-202, 222-223, and 226-230 are pending.

Newly submitted claims 256-312 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly recited limitations that were not included in the original search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 256-312 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

Claims 170-176, 180, 199-202, 222-223, and 226-230 stand rejected under 35 U.S.C. 103(a) as being anticipated by Diamond (Proc. Natl. Acad. Sci., vol. 93, pp 5156-5160, May 1996) in view of Julius (USPN 6,093,693).

The claimed invention is drawn to a method of stimulating expression of defensin by administering a compound comprising soluble CD14 to epithelial cells of a mammal. The protein has an amino acid sequence of at least about 63%, 68%, 71%, 73%, 78% 83%, 88%, 93%, or 98% conserved in relation to SEQ ID NO:4.

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Diamond teaches tracheal epithelial cells exposed to bacterial lipopolysaccharides express CD14, see abstract. Diamond discloses a widespread mechanism of host defense in the animal kingdom is the production of antibiotic peptides/ defensins, see page 5156, column 1, paragraph 2. Diamond teaches the soluble form of CD14 can mediate lipopolysaccharide-stimulated responses in epithelial cells, see page 5157, column 2, paragraph 4. Diamond discloses *in vivo* evidence for increased expression of *B*-defensin lingual antibiotic peptide in the squamous epithelium of the tongue, see page 5159, column 2, paragraph 2. Diamond does not teach a structure of CD14.

Julius teaches a method of activating B cells in a mammal, by administering CD14, see abstract. Julius discloses SEQ ID NO: 4 which is a 100% query match with SEQ ID NO:4 of the instant application, see STIC search. Julius teaches that CD14 can be administered to an infant, by incorporating CD14 into infant formula, see abstract. Julius discloses CD14 protein purified from bovine colostrum whey, see abstract.

Applicant's arguments were carefully considered but were not found persuasive ,

Applicant contends that the invention defined by the claims require stimulating or enhancing expression of at least one defensin by directly exposing epithelial cells or epidermis to soluble CD14 (or equivalent), is neither taught, nor suggested by the teachings of Diamond, alone or in combination with Julius. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have added the teachings of Diamond to protein of Julius in order to enhance expression of antibiotic peptides/ defensins because Diamond teaches that many mammalian epithelial cells have the capacity for analogous host defense responses. Applicant further contends that administering the compound in the form

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of an aerosol is not taught in the cited references. The examiner contends that this is a matter of judicious selection for one of ordinary skill in the art at the time the invention was made.

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

RT

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3/4/05

RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER